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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/557,696 04/25/00 BIХ N19.12-0035 **EXAMINER** IM71/0706 PETER S DARDI PH D GORDON R WESTERMAN CHAMPLIN & KELLY ART UNIT PAPER NUMBER 900 SECOND AVENUE SOUTH INTERNATIONAL CENTRE - SUITE 1600 1743 MINNEAPOLIS MN 55402-3319 DATE MAILED: 07/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary		Application No.	Applicant(s)	
		09/557,696	BI ET AL.	
		Examiner	Art Unit	
		Brian R. Gordon	1743	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status				
1)	Responsive to communication(s) filed on 25	<u> April 2000</u> .		
2a)□	This action is FINAL . 2b)⊠ TI	his action is non-final.		
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims				
4)🖂	4) Claim(s) 1-38 is/are pending in the application.			
4a) Of the above claim(s) <u>15-38</u> is/are withdrawn from consideration.				
5)[5) Claim(s) is/are allowed.			
6)⊠	6)⊠ Claim(s) <u>1-7, 12, and 14</u> is/are rejected.			
7)	7) Claim(s) <u>8-11, and 13</u> is/are objected to.			
8)⊠	8) Claims 1-38 are subject to restriction and/or election requirement.			
Application Papers				
9) The specification is objected to by the Examiner.				
10)⊠ The drawing(s) filed on <u>25 April 2000</u> is/are objected to by the Examiner.				
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved.				
12)	The oath or declaration is objected to by the E	xaminer.		
Priority under 35 U.S.C. § 119				
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).				
a) All b) Some * c) None of:				
1. Certified copies of the priority documents have been received.				
2. Certified copies of the priority documents have been received in Application No				
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).				
	* See the attached detailed Office action for a list of the certified copies not received.			
14)⊠ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).				
Attachmen	nt(s)			
16) 🔯 Not	ice of References Cited (PTO-892) ice of Draftsperson's Patent Drawing Review (PTO-948) ormation Disclosure Statement(s) (PTO-1449) Paper No(s)	19) Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)	

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DETAILED ACTION

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Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-14, drawn to a method for obtaining a plurality of quantities of compositions with an apparatus comprising a plurality of collectors, the method comprising reacting a first quantity of fluid reactants to form a first quantity of product, collecting the first product with first collector, reacting a second quantity of reactants to form a second materially different product, and collecting the second product with a second collector, classified in class 436, subclass 180.
- II. Claims 15-31, drawn to an apparatus comprising a nozzle connected to a reactant source, a plurality of collectors, wherein the nozzle and the plurality of collectors move relative to each other such that a collector can be selectively placed to receive a fluid stream emanating from the nozzle, each collector comprising a gas permeable membrane, classified in class 422, subclass 134.
- III. Claims 32-34, drawn to an apparatus comprising a nozzle connected to a reactant source, a plurality of collectors, wherein the nozzle and the plurality of collectors move relative to each other such that a collector can be selectively placed to receive a fluid stream emanating from the nozzle, a product composition within the fluid stream, classified in class 422, subclass 134.
- IV. Claims 34-37, drawn to a method for rapid evaluation of the properties of particles, the method comprising collecting a plurality of quantities of particles

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wherein each quantity of particles is collected using a separate particle collector comprising a gas permeable membrane; and evaluating a property of each quantity of particles in contact with the gas permeable membrane, classified in class 436, subclass 50.

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V. Claim 38, drawn to a method of producing a mixture of compositions, the method comprising reacting a first quantity of fluid reactants to form a first quantity of product, collecting the first product with a collector, reacting a second quantity of reactants to form a second materially different product, and collecting the second product using the collector, classified in class 436, subclass 180.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and (II or III) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process of group I can be practice by hand, for one can perform reactions and subsequently separate and collect the product through various separation methods such as filtration. The apparatus could also be used specifically just to dispense a fluid into a plurality of containers.
- 3. Inventions IV and (I or V) are related as combination and subcombination.

 Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other

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combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination, group IV, does not require the steps of forming a first and second product through reactions. The subcombination, group (I or V) has separate utility such as forming and collecting product compositions.

- 4. Inventions III and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination group III does not require that the collector comprise a gas permeable membrane. The subcombination has separate utility such as to filter or collect gases from the stream.
- 5. Inventions (IV or V) and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus of group II could be used to filter a fluid as it is dispensed to a collector for the device does not require any evaluations of properties or reacting any fluids to form a product.
- 6. Inventions (IV or V) and III are related as process and apparatus for its practice.

 The inventions are distinct if it can be shown that either: (1) the process as claimed can

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be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus of group III can be used to practice another method such as dispensing a reactant or into a collector to be stored, shipped, or etc.

- 7. Inventions IV and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination, group IV, does not require the steps of forming a first and second product through reactions. The subcombination, group V has separate utility such as forming (reacting) and collecting product compositions.
- 8. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-V, restriction for examination purposes as indicated is proper.
- 9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 10. During a telephone conversation with Peter Dardi on June 22, 2001 a provisional election was made with traverse to prosecute the invention of Group 1, claims 1-14.

 Affirmation of this election must be made by applicant in replying to this Office action.

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Claims 15-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

- 12. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.
- 13. The drawings are objected to because there is designated labeling of Figure 3. Correction is required.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- 15. Claims 1, 2, 5-7,and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Tayi US 6,096,561.

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Tayi discloses an apparatus and method for simultaneously performing at least two assays using certain reagents for a plurality of liquid samples on a continuous analytical system is disclosed. The method comprising the steps of combining an aliquot of each liquid sample with at least one reagent in a first reaction container to form a first assay reaction for each liquid sample, and combining an aliquot of each liquid sample with at least one of the other reagents in a second reaction container to form a second assay reaction for each liquid sample. The method further comprises the steps of incubating the assay reactions of each assay being conducted at least one time, and performing other activities associated with each assay and using the first and second assay reactions to complete each assay, including analyzing the incubated assay reactions. The method finally comprises the step of scheduling the steps of combining, incubating, and performing other activities associated with each of the assays according to a predetermined protocol.

The methodology of the automated immunoassay analytical system is achieved through the use of a self-container, fully automated, continuous and random access instrument comprising a main carousel assembly consisting of the reagent pack carousel, a reaction vessel carousel and a test sample container carousel concentrically and independently rotatable. The main carousel assembly is provided with a transfer pipette operated by a boom arm for transferring and kitting test sample and reagents into the reaction vessel automatically following a predetermined test schedule. The main carousel assembly is provided with bar code readers for reagent packs and test sample containers and has the capability of aligning the reagent pack carousel and test

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sample container carousel and a reaction vessel for pipette transfer operations. Once the assay to be performed is scheduled, the reaction vessel carousel, the reagent pack carousel and the test sample container carousel are rotated until the reaction vessel, a reagent pack and a test sample container, respectively, are determined to be in the transfer pipette access position. The transfer pipette then transfers the test sample from the test sample container and, depending upon the assay to be performed, the reagents from the reagent pack are transferred to the reaction vessel. The reaction vessel carousel is then rotated to a transfer station position which contacts the reaction vessel with a transfer mechanism and pulls the reaction vessel into the transfer station. The reaction vessel is then loaded onto the process carousel by the transfer mechanism.

The device also performs chemiluminescent tests which allow for the evaluations of the assays.

Claim Rejections - 35 USC § 103

- 16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 3-4, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tayi 6,096,561.

Tayi does not specifically state that the reaction conditions of the first and second reactions are different.

However, the method of Tayi does incorporate the usage of an incubation source.

It would have been obvious to one of the ordinary skill in the art at the time of the invention to vary the incubation temperature of the different assays to observe the different results of varying the energy input of the incubation on the reacting assays.

As to claim 14, Tayi does not recite that the device employs two different nozzles.

It would have been obvious to one of the ordinary skill in the art at the time of the invention to provide two different nozzles in order to avoid cross-contamination within the sample containers as well as to eliminate the possibility of unwanted reactions occurring within the nozzle itself.

Allowable Subject Matter

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19. Claims 8-11 and 13-14 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. The following is a statement of reasons for the indication of allowable subject matter: Tayi does not disclose a method for obtaining a plurality of quantities to compositions wherein the method comprises providing an apparatus that has a radiation path defined by a radiation source (infrared laser) and directing optical elements wherein the reacting of the fluid reactants involves interacting radiation source with the reactants. The apparatus comprises pumps and valves that allow for the first collector to be exposed to the forces of the pump while the first particles are collected and the second collector is exposed to the forces of the pump while the second particles are collected. The step of introducing the reactants into a reaction zone through a plurality of inlets or nozzles to allow for mixing.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Saneii discloses a solid phase peptide synthesizer.

Imai et al disclose an automatic analyzing method.

Yamashita et al. disclose an automatic chemical analyzing method and device.

Mitsumaki et al. disclose an automatic processor.

Koike discloses an automatic solid phase extraction device.

Hager et al. disclose a method for controlling the conversion of iron in a reactor.

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Laska et al disclose a method and apparatus for effecting a plurality of assays.

Kirk et al. disclose a high throughput chemical synthesis system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7719 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

BRG July 2, 2001 Jill Warden
Supervisory Patent Examiner
Technology Center 1700